DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Medtronic, Inc.
Lisa Stone
Principal Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, MN 55112

Re: K142784
Trade/Device Name: Affinity Fusion® Oxygenator with Integrated Arterial Filter and with Balance ™ Biosurface or Carmeda® BioActive Surface
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: September 26, 2014
Received: September 26, 2014

Dear Ms. Stone:

This letter corrects our substantially equivalent letter of October 24, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142784

Device Name

Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface

Indications for Use *(Describe)*

The Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to six hours in duration.

The Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface is designed to filter from the circuit microemboli larger than the specified micron size for periods up to six hours during cardiopulmonary bypass surgery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
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Paperwork Reduction Act (PRA) Staff
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142784

Device Name
Affinity Fusion Oxygenator with Integrated Arterial Filter and Carmeda Bio-Active Surface

Indications for Use *(Describe)*
The Affinity Fusion Oxygenator with Integrated Arterial Filter and Carmeda Bio-Active Surface is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to six hours in duration.

The Affinity Fusion Oxygenator with Integrated Arterial Filter and Carmeda Bio-Active Surface is designed to filter from the circuit microemboli larger than the specified micron size for periods up to six hours during cardiopulmonary bypass surgery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary of Safety and Effectiveness

Date Prepared: September 23, 2014

Applicant:
Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
Brooklyn Park, MN 55428
Establishment Registration No. 2184009

Contact Person:
Lisa Stone
Principal Regulatory Affairs Specialist
Medtronic, Inc.
Coronary and Structural Heart Disease Management
8200 Coral Sea Street NE, MVS 83
Mounds View, MN 55112
Phone: (763) 514-9866
Fax: (763) 367-8147
Email: lisa.j.stone@medtronic.com

Trade Name: Affinity Fusion® Oxygenator with Integrated Arterial Filter and with Balance™ Biosurface or Carmeda® BioActive Surface

Common Name: Oxygenator

Classification Name: Cardiopulmonary Bypass Oxygenator

Classification: Class II, 21 CFR 870.4350

Product Code: DTZ

Name of Predicate Device: Affinity Fusion® Oxygenator with Integrated Arterial Filter and with Balance™ Biosurface, Model BB811 (K122827)

Affinity Fusion® Oxygenator with Integrated Arterial Filter and with Carmeda® BioActive Surface, Model CB811 (K123314)

Device Description

Affinity Fusion Oxygenators with Integrated Arterial Filter and with Balance Biosurface or Carmeda BioActive Surface are single-use, microporous, hollow-fiber, gas exchange device with plasma-resistant fiber and integrated heat exchanger and arterial filter. The oxygenators are bonded on their primary blood contacting surfaces with either Balance Biosurface or Carmeda BioActive Surface.

The device is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood. The device is also used to cool or warm the blood during routine cardiopulmonary bypass procedures up to six hours in duration. The integrated filter is designed to filter from the extracorporeal circuit microemboli larger than the specified micron size (25µ). The filtration functionality is achieved through the progressively tighter fiber spacing within the fiber bundle assembly (FBA) inside the oxygenator.

The purpose of this Special 510(k) Notification was to notify the FDA of an alternate material formulation for the luer caps used on the recirculation, cardioplegia and sampling ports of the Affinity Fusion Oxygenator with Integrated Filter and with either Balance Biosurface or Carmeda BioActive Surface.

Intended Use

There were no changes to the intended use of the devices as related to the change purposed in this Special 510(k) Notification. The current Indications for Use statement is noted below:

Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface (Model BB811)

The Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to six hours in duration.

The Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface is designed to filter from the circuit microemboli larger than the specified micron size for periods up to six hours during cardiopulmonary bypass surgery.

Affinity Fusion Oxygenator with Integrated Arterial Filter and Carmeda BioActive Surface (Model CB811)

The Affinity Fusion Oxygenator with Integrated Arterial Filter and Carmeda BioActive Surface is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to six hours in duration.

The Affinity Fusion Oxygenator with Integrated Arterial Filter and Carmeda BioActive Surface is designed to filter from the circuit microemboli larger than the specified micron size for periods up to six hours during cardiopulmonary bypass surgery.

Comparison to the Predicate Device

The Affinity Fusion Oxygenators with Integrated Filter and with Balance Biosurface or Carmeda BioActive Surface are substantially equivalent to the previous versions (predicate) of these devices.

The modified oxygenators have the following similarities to the predicate devices which received 510(k) clearance:

- Same intended use/indications
- Same operating principle
- Same fundamental technological characteristics
- Same overall design, dimensions and performance
- Substantially equivalent materials – All materials are the same except for the protective luer caps used on the recirculation, cardioplegia and sampling ports. These caps have undergone a minor formulation change.
- Same packaging materials and design
- Same sterilization requirements

Summary of Performance Data

Bench testing was used to verify the performance characteristics of these devices. Clinical testing was not required to establish substantial equivalence.

The following performance tests were conducted:

- Biocompatibility
- Positive pressure integrity

Conclusion

In summary, the information included in this submission demonstrates that with changes made to the Affinity Fusion Oxygenators with Integrated Filter and with Balance Biosurface or Carmeda BioActive Surface are substantially equivalent to the legally marketed predicate versions.